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| 10/713,029                       | 11/17/2003  | Young-Meng Chiang    | 05085ZEN-US         | 9753             |
| 46103                            | 7590        | 05/11/2009           |                     |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/713,029

Applicant(s)

CHIANG ET AL.

Examiner

BRENT PAGE

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 3, 4 and 6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5 and 7-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

Applicant's election without traverse of Group III, claims 1-2, 5, and 7-18 in the reply filed on 02/12/2007 is acknowledged. This Office Action is repeated from the office action mailed 04/23/2007 to allow Applicant to respond to the rejections of record.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 5 and 7-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "high optical density". It is unclear what constitutes a "high" optical density, and/or what limitation is intended for the claim. It is not expressly stated what the optical density is being compared to, for it to be "high", and thus for lack of comparative examples, it is not considered limiting.

Claims 2-6 all recite genus names. The genus names should be italicized.

Claim 9 recites "fresh air for keeping said minute segments to be suspended". It is unclear how fresh air keeps minute segments suspended. Is air bubbling through? Claim 9 also recites "larger tank" and "minute segments", both terms lack a comparative basis. New Matter should be avoided in any amendment.

Claim 10 recites "wherein the better temperature...". It is unclear what the claimed conditions are supposed to be "better" than. It is further unclear what "better" means, whether it

means obtaining a higher yield, higher purity, higher success rate, etc. Furthermore, "better" lacks an antecedent basis.

Claim 12 recites "wherein the method of drying...", however claim 1 from which claim 12 depends does not recite a method of drying, and therefore it lacks antecedent basis.

Claims 14 and 15 appear to be reciting a chemical formula. However, the claimed subject matter appears to contain typographical errors. The claims both recite "(NH.sub.4).sub.2 SO.sub.4". It is unclear whether this is meant to mean  $-(\text{NH}_4)_2\text{SO}_4-$ , or whether there is another meaning associated with this phrase. Applicant should either correct the typographical error, or make it clear what .sub. means. For the purposes of examination, the claims were interpreted to contain  $-(\text{NH}_4)_2\text{SO}_4-$ .

Claim 14 also recites "the 20% solution" without any previous mention of such solution in the claims and therefore lacks antecedence.

Claim 15 also recites "the 60-65% solution" without any previous mention of such solution in the claims and therefore lacks antecedence.

Claim 17 recites a trademark, which must be in all capital letters.

New Matter should be avoided upon amendment of the claims.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 5, 7-12 and 14-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for water or potassium phosphate liquid solution pH 5-10 and salting out using 20% solution of  $(\text{NH}_4)_2\text{SO}_4$ , does not reasonably provide enablement for

any solution with a pH anywhere from 5-10 and salting out by any method. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are broadly drawn to a method for producing phycoerythrin wherein one of the method steps is adding cultivated filaments to a liquid solution with the pH value of 5-10.

In contrast the specification only provides guidance for adding a potassium phosphate solution or water and does not provide guidance for any other solutions within the pH range that would enable one to successfully produce phycoerythrin.

It is unpredictable which liquid solution of pH 5-10 would be capable of cultivating filaments without disrupting the phycoerythrin processing. Not all liquids would reasonably be expected to achieve the desired effect, and more than routine experimentation would be required to test the hundreds of thousands of liquids as broadly claimed for their cultivating capabilities. It would further be unpredictable which salts and at what concentration they would be capable of purifying phycoerythrin. Some concentrations and salts may materially alter the structure, activity or purity of the phycoerythrin.

Given the state of the art, it would be undue experimentation for one of skill in the art to test and all solutions pH 5-10 and evaluate them for their ability to obtain phycoerythrin in the claimed method.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, and 7-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Chiang et al (US Patent 5358858).

The claims are drawn to a method for producing phycoerythrin comprising cultivating a gametophyte with mature tetrasporangia in a medium to obtain tetraspores, cultivating the tetraspores in a condition that the temperature, light intensity and light/dark ratio are respectively 15-30 C, 500 lux-6000 lux and above 10:14 to germinate filaments, collecting said filaments, adding filaments to a liquid solution with the pH value of 5-10, wherein the liquid consists of water and potassium phosphate, obtaining a clear-red pigment protein solution containing phycoerythrin by centrifuging said liquid solution at 6000 rpm for 10 minutes at 4 C and salting out the gel-form phycoerythrin concentrate from said protein solution wherein said gametophyte is from algae, wherein the medium is a SWM-III medium, wherein the medium is an inorganic SWM-III medium, wherein the step of cultivating tetraspores to germinate filaments further comprises breaking up said filaments into minute segments and cultivating them in a larger tank in the same condition until the cultivated filaments grow to the required amounts, wherein said tank is supplied with fresh air, wherein the better temperature, light intensity and light/dark ratio of said condition are respectively 20 C, 2000 lux, and 12:12, wherein the step of collecting the filaments further comprises collecting filaments by a net of 20-400 mesh, drying said filaments and grinding filaments into powder, wherein the drying is selected from the vacuum method or the warm air method, wherein the salting out the gel-form phycoerythrin further comprises adding the 20% solution of (NH<sub>4</sub>)<sub>2</sub>SO<sub>4</sub>, or the 60~65%

solution of said content to said protein solution and centrifuging said protein solution at 6000 rpm for 10 minutes at 4 C, and wherein the salting out the gel-form phycoerythrin further comprises dialyzing the phycoerythrin by gel filtration, wherein the gel filtration is a Sephadex G200 gel filtration and wherein purifying said gel-form phycoerythrin concentrate is by ultrafiltration.

Chiang et al teach a method for producing phycoerythrin comprising cultivating a mature thalli in a medium to obtain spores, cultivating the spores in a condition that the temperature, light intensity and light/dark ratio are respectively 15-30 C, 500 lux-6000 lux and above 10:14 to germinate filaments (see Column 2 lines 18-32, for example), collecting said filaments, adding filaments to a liquid solution with the pH value of 5-10, wherein the liquid consists of water and potassium phosphate (see Example 10, lines 33-35 in particular, for example), obtaining a clear-red pigment protein solution containing phycoerythrin by centrifuging said liquid solution at 6000 rpm for 10 minutes at 4 C (see Example 10, for example) and salting out the gel-form phycoerythrin concentrate from said protein solution wherein said gametophyte is from *Porphyra Angusta*, wherein the medium is a SWM-III medium, wherein the medium is an inorganic SWM-III medium (see claims 1 and 3, for example), wherein the step of cultivating tetraspores to germinate filaments further comprises breaking up said filaments into minute segments and cultivating them in a larger tank in the same condition until the cultivated filaments grow to the required amounts, wherein said tank is supplied with fresh air (see claim 1 and see Column 2 lines 32-41, for example), wherein the better temperature, light intensity and light/dark ratio of said condition are respectively 20 C, 2000 lux, and 12:12 (see in particular, Example 13), wherein the step of collecting the filaments further comprises collecting filaments

by a net of 20-400 mesh (see Column 2 lines 42-43 and claim 7, for example), drying said filaments and grinding filaments into powder, wherein the drying is selected from the vacuum method or the warm air method (see claims 5 and 6 , for example) , wherein the salting out the gel-form phycoerythrin further comprises adding the 20% solution of (NH.sub.4).sub.2 SO.sub.4, or the 60-65% solution of said content to said protein solution and centrifuging said protein solution at 6000 rpm for 10 minutes at 4 C (see Example 10 in particular, and also claim 8, for example), and wherein the salting out the gel-form phycoerythrin further comprises dialyzing the phycoerythrin by gel filtration, wherein the gel filtration is a Sephadex G200 gel filtration and wherein the purification is done by ultrafiltration (see claim 9 and Example 21, for example).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 5, and 7-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chiang et al (US Patent 5358858).

The claims are drawn to a method for producing phycoerythrin comprising cultivating a gametophyte with mature tetrasporangia in a medium to obtain tetraspores, cultivating the tetraspores in a condition that the temperature, light intensity and light/dark ratio are respectively 15-30 C, 500 lux-6000 lux and above 10:14 to germinate filaments, collecting said



filaments, adding filaments to a liquid solution with the pH value of 5-10, wherein the liquid consists of water and potassium phosphate, obtaining a clear-red pigment protein solution containing phycoerythrin by centrifuging said liquid solution at 6000 rpm for 10 minutes at 4 C and salting out the gel-form phycoerythrin concentrate from said protein solution wherein said gametophyte is from *Helminthocladia australis*, wherein the medium is a SWM-III medium, wherein the medium is an inorganic SWM-III medium, wherein the step of cultivating tetraspores to germinate filaments further comprises breaking up said filaments into minute segments and cultivating them in a larger tank in the same condition until the cultivated filaments grow to the required amounts, wherein said tank is supplied with fresh air, wherein the better temperature, light intensity and light/dark ratio of said condition are respectively 20 C, 2000 lux, and 12:12, wherein the step of collecting the filaments further comprises collecting filaments by a net of 20-400 mesh, drying said filaments and grinding filaments into powder, wherein the drying is selected from the vacuum method or the warm air method, wherein the salting out the gel-form phycoerythrin further comprises adding the 20% solution of (NH.sub.4).sub.2 SO.sub.4, or the 60~65% solution of said content to said protein solution and centrifuging said protein solution at 6000 rpm for 10 minutes at 4 C, and wherein the salting out the gel-form phycoerythrin further comprises dialyzing the phycoerythrin by gel filtration, wherein the gel filtration is a Sephadex G200 gel filtration and wherein purifying said gel-form phycoerythrin concentrate is by ultrafiltration.

Chiang et al teach a method for producing phycoerythrin comprising cultivating a mature thalli in a medium to obtain spores, cultivating the spores in a condition that the temperature, light intensity and light/dark ratio are respectively 15-30 C, 500 lux-6000 lux and above 10:14

to germinate filaments (see Column 2 lines 18-32, for example), collecting said filaments, adding filaments to a liquid solution with the pH value of 5-10, wherein the liquid consists of water and potassium phosphate (see Example 10, lines 33-35 in particular, for example), obtaining a clear-red pigment protein solution containing phycoerythrin by centrifuging said liquid solution at 6000 rpm for 10 minutes at 4 C (see Example 10, for example) and salting out the gel-form phycoerythrin concentrate from said protein solution wherein said gametophyte is from *Porphyra Angusta*, wherein the medium is a SWM-III medium, wherein the medium is an inorganic SWM-III medium (see claims 1 and 3, for example), wherein the step of cultivating tetraspores to germinate filaments further comprises breaking up said filaments into minute segments and cultivating them in a larger tank in the same condition until the cultivated filaments grow to the required amounts, wherein said tank is supplied with fresh air (see claim 1 and see Column 2 lines 32-41, for example), wherein the better temperature, light intensity and light/dark ratio of said condition are respectively 20 C, 2000 lux, and 12:12 (see in particular, Example 13), wherein the step of collecting the filaments further comprises collecting filaments by a net of 20-400 mesh (see Column 2 lines 42-43 and claim 7, for example), drying said filaments and grinding filaments into powder, wherein the drying is selected from the vacuum method or the warm air method (see claims 5 and 6 , for example) , wherein the salting out the gel-form phycoerythrin further comprises adding the 20% solution of (NH.sub.4).sub.2 SO.sub.4, or the 60-65% solution of said content to said protein solution and centrifuging said protein solution at 6000 rpm for 10 minutes at 4 C (see Example 10 in particular, and also claim 8, for example), and wherein the salting out the gel-form phycoerythrin further comprises dialyzing the phycoerythrin by gel filtration, wherein the gel filtration is a Sephadex G200 gel

filtration and wherein the purification is done by ultrafiltration (see claim 9 and Example 21, for example).

Chiang et al do not teach the above method as applied to *Helminthocladia australis*. However, it would have been obvious to one of ordinary skill in the art to isolate phycoerythrin from any tissue containing phycoerythrin from any species containing phycoerythrin as long as nothing further than routine optimization is required for successful isolation and purification. The claimed properties of the extracted phycoerythrin from claim 5, are considered to be inherent properties that do not limit the claimed method, but rather describe the resulting product.

In the instant case, it would have been obvious to one of skill in the art to apply the method taught by Chiang et al to *Helminthocladia australis* since all of the claimed conditions are present in the prior art, and no further steps are required for gametophytic tissue. The same medium, same conditions and same purification is applied as claimed, without even any routine optimization. Even if routine optimization would have been required, several examples are provided by Chiang et al that would have rendered any routine optimization obvious to one of ordinary skill in the art. One would have been further motivated to apply the method by Chiang et al to the above stated tissues by Chiang et al's statement "However, the quantity of phycoerythrin is still few and the price is high due to the shortage of raw material available and the difficulty in processing for the commercial production of phycoerythrin".

No claims are free of the prior art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brent Page whose telephone number is (571)-272-5914. The examiner can normally be reached on Monday-Friday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phuong T. Bui/  
Primary Examiner, Art Unit 1638

Brent T Page